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tase 8:25-cv-00097-MWC-DFM Document 1

Plaintiff Barbara Sheridan ("Plaintiff"), by and through her undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Edwards Lifesciences Corporation ("Edwards" or the "Company"), against current and former members of the Company's Board of Directors (the "Board") and certain of its executive officers seeking to remedy the Individual Defendants' (defined below) breach of fiduciary duties and violations of federal law. Plaintiff alleges the following based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' publicly available documents, filings with the United States Securities and Exchange Commission ("SEC"), press releases published by and regarding Edwards, legal filings, news reports, securities analysts' reports about the Company, the securities class action *Patel v. Edwards Lifesciences Corporation et al*, Case No. 8:24-cv-02221-AH-KES (C.D. Cal.) (the "Securities Class Action"), and other publicly available information.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought by Plaintiff on behalf of Edwards against certain of its officers and current and former members of the Company's Board (the "Individual Defendants")¹ for breaches of their fiduciary duties between at least February 6, 2024 and July 24, 2024, inclusive (the "Relevant Period"), and the federal securities laws, as set forth below.

¹ Individual Defendants are Bernard J. Zovighian ("Zovighian"), Nicholas J. Valeriani ("Valeriani"), Leslie C. Davis ("Davis"), Kieran T. Gallahue ("Gallahue"), Leslie S. Heisz ("Heisz"), Paul A. LaViolette ("LaViolette"), Steven R. Loranger ("Loranger"), Ramona Sequeira ("Sequeira"), Martha H. Marsh ("Marsh"), Michael A. Mussallem ("Mussallem"), Larry L. Wood ("Wood"), and Scott B. Ullem ("Ullem"). The Individual Defendants, together with Edwards, are "Defendants."

- 2. Edwards is an American medical technology company headquartered in Irvine, California, specializing in artificial heart valves and hemodynamic monitoring. The Company's products and technologies are categorized into four main groups: Transcatheter Aortic Valve Replacement ("TAVR"), Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care.
- 3. The TAVR segment includes Edwards' transcatheter heart valve replacement technologies, which are designed for the minimally-invasive replacement of aortic heart valves. The Company's catheter-based approaches for treating patients who have severe symptomatic aortic stenosis include the "Sapien" family of valves, such as the Edwards SAPIEN 3, the Edwards SAPIEN 3 Ultra, and the Edwards SAPIEN 3 Ultra RESILIA systems. The SAPIEN family of valves are the most widely implanted transcatheter heart valves in the world.
- 4. As detailed herein, throughout the Relevant Period, the Individual Defendants repeatedly provided investors with material information concerning Edwards' expected revenue for the fiscal year 2024, particularly as it related to the growth of the Company's TAVR products. For instance, in a press release and during an earnings call on February 6, 2024, Defendants assured investors that "next-gen TAVR and additional evidence on asymptomatic and moderate AS patients position [the Company] for healthy, sustainable TAVR growth well into the future" and expressed confidence that "the future of TAVR remains strong[,]" driven by "increased focus on patient activation, a platform that delivers lifetime management for aortic stenosis patients, advances in new technologies such as RESILIA tissue, as well as indication expansion and increased global adoption."
- 5. The truth was revealed on July 24, 2024, however, when Edwards announced below-expectation financial results for the second quarter of fiscal 2024 and cut its revenue guidance for the TAVR platform for the full fiscal year 2024. The Company attributed the TAVR setback on the "continued growth and"

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- expansion of structural heart therapies ... [which] put pressure on hospital workflows." Despite continued claims during the Relevant Period of confidence in Edwards' ability to capitalize on a subset of untreated patients through scaling of its various patient activation activities, Defendants admitted they "probably underestimated the burden of even starting these new programs, even preparing to start these new programs..."
- 6. On this news, Edwards' stock price fell \$27.25 per share, or 31.3%, from a closing price of \$86.95 per share on July 24, 2024 to close at \$59.70 per share on July 25, 2024.
- 7. As set forth herein, throughout the Relevant Period the Individual Defendants breached their fiduciary duties by issuing, causing the issuance of, and/or failing to correct the materially false and/or misleading statements and omissions of material fact to the investing public concerning the Company's business, operations, and prospects. Specifically, the Individual Defendants created the false impression that they had reliable information regarding the Company's projected revenue and anticipated growth, while failing to disclose: (i) risk from seasonality and macroeconomic fluctuations were underplayed; (ii) the Individual Defendants' model for growth relied too heavily, or otherwise overstated, hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies; (iii) as a result, there was a significant risk that TAVR's growth would decelerate; and (iv) the Company lacked internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.
- 8. Additionally, in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain adequate internal controls.
 - 9. Furthermore, the Individual Defendants breached their fiduciary

- 10. As a result of the foregoing, the Securities Class Action was filed against the Company, Chief Executive Officer ("CEO") Bernard Zovighian, Chief Financial Officer ("CFO") Scott Ullem, and Group President of TAVR Larry Wood on October 14, 2024.
- 11. As a direct and proximate result of the Individual Defendants' misconduct, the Company has incurred significant financial losses, including the cost of defending and paying class-wide damages in the Securities Class Action, as well as additional losses, including reputational harm and loss of goodwill.
- 12. Moreover, in light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company's current directors, their collective engagement in fraud, the substantial likelihood of the directors' liability in this derivative action and Defendants' liability in the Securities Class Action, their being beholden to each other, their longstanding business and personal relationships with each other, and their not being disinterested and/or independent directors, a majority of Edwards' Board cannot consider a demand to commence litigation against themselves and the other Individual Defendants on behalf of the Company with the requisite level of disinterestedness and independence. Accordingly, Plaintiff did not make a demand on the Board because, as further detailed herein, demand would be a futile and useless act.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act") over the claims asserted herein for violations of Sections 14(a) of the Exchange Act (15 U.S.C. §§ 78n(a) and SEC Rule 14a-9 (17 C.F.R.§240.14a-9) promulgated

- 14. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).
- 15. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.
- 16. In connection with the acts, conduct and other wrongs complained of herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mail, and the facilities of a national securities market.
- 17. Venue is proper in this District pursuant to Section 27(a) of the Exchange Act and 28 U.S.C. § 1391 and 1401 because a substantial portion of the acts and omissions alleged herein, including the dissemination of materially false and misleading information, occurred in this District, Edwards is headquartered in this District, Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District, and the Securities Class Action is pending in this District.

PARTIES

Plaintiff

18. Plaintiff is, and has been at all relevant times, a shareholder of Edwards.

Nominal Defendant

19. Nominal Defendant Edwards is incorporated under the laws of Delaware with its principal executive offices located at One Edwards Way, Irvine, California 92614. Edwards' common stock is traded on the New York Stock Exchange ("NYSE") under the ticker symbol "EW."

Individual Defendants

20. Defendant Zovighian has served as the Company's CEO and as a

- 21. Defendant Valeriani has served as a member of the Board since 2014 and as Chair of the Board since May 2024. Defendant Valeriani also serves as Chair of the Board's Compensation and Governance Committee. As set forth in the 2024 Proxy, Defendant Valeriani received \$347,972 in compensation from the Company in 2023. Also according to the 2024 Proxy, Defendant Valeriani beneficially owned 66,111 shares of the Company's common stock as of January 31, 2024.
- 22. Defendant Davis has served as a member of the Board since May 2024. Defendant Davis also serves as a member of the Board's Compensation and Governance Committee.
- 23. Defendant Gallahue has served as a member of the Board since 2015. Defendant Gallahue also serves as a member of the Board's Audit Committee. As set forth in the 2024 Proxy, Defendant Gallahue received \$335,056 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Gallahue beneficially owned 70,277 shares of the Company's common stock as of January 31, 2024.
- 24. Defendant Heisz has served as a member of the Board since 2016. Defendant Heisz also serves as Chair of the Board's Audit Committee. As set forth in the 2024 Proxy, Defendant Heisz received \$356,422 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Heisz beneficially

- 25. Defendant LaViolette has served as a member of the Board since 2020. Defendant LaViolette also serves as a member of the Boards' Compensation and Governance Committee. As set forth in the 2024 Proxy, Defendant LaViolette received \$329,972 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant LaViolette beneficially owned 4,915 shares of the Company's common stock as of January 31, 2024.
- 26. Defendant Loranger has served as a member of the Board since 2016. Defendant Loranger also serves as a member of the Board's Audit Committee. As set forth in the 2024 Proxy, Defendant Loranger received \$335,056 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Loranger beneficially owned 80,760 shares of the Company's common stock as of January 31, 2024.
- 27. Defendant Sequeira has served as a member of the Board since 2020. Defendant Sequeira also serves as a member of the Board's Audit Committee. As set forth in the 2024 Proxy, Defendant Sequeira received \$334,972 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Sequeira beneficially owned 8,218 shares of the Company's common stock as of January 31, 2024.
- 28. Defendant Marsh served as a member of the Board from 2015 until May 7, 2024. During her time on the Board, Defendant Marsh served as the Lead Independent Director and as a member of the Compensation and Governance Committee. According to the 2024 Proxy, Defendant Marsh received \$364,972 in compensation from the Company in 2023.
- 29. Defendant Mussallem served as a member of the Board and as Chairman of the Board from 2000 until his retirement effective May 7, 2024. Defendant Mussallem also served as the Company's CEO from 2000 until May

- 30. Defendant Wood has served as the Company's Corporate Vice President and Group President, TAVR and Surgical Structural Heart since January 2023. Defendant Wood previously served as Corporate Vice President, TAVR, since 2007. As set forth in the 2024 Proxy, Defendant Wood received \$5,395,034 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Wood beneficially owned 372,945 shares of the Company's common stock as of January 31, 2024. Defendant Wood is also named as a defendant in the Securities Class Action.
- 31. Defendant Ullem has served as the Company's Corporate Vice President and CFO since 2014. As set forth in the 2024 Proxy, Defendant Ullem received \$5,949,153 in compensation from the Company in 2023. According to the 2024 Proxy, Defendant Ullem beneficially owned 490,188 shares of the Company's common stock as of January 31, 2024. Defendant Ullem is also named as a defendant in the Securities Class Action.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

- 32. By reason of their positions as officers and/or directors of Edwards, and because of their ability to control the business and corporate affairs of Edwards, the Individual Defendants owed Edwards and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Edwards in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Edwards and its shareholders.
 - 33. Each director and officer of the Company owes to Edwards and its

shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligation of fair dealing.

- 34. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Edwards, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.
- 35. To discharge their duties, the officers and directors of Edwards were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.
- 36. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officers of Edwards, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.
- 37. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NYSE, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, financial statements, products, management, internal controls, earnings, and present and future business prospects, including the dissemination of false and/or materially misleading information regarding the Company's business, prospects, and

operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful, accurate, and fairly presented information.

- 38. To discharge their duties, the officers and directors of Edwards were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Edwards were required to, among other things:
 - (i) Ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of California, Delaware, and the United States, and pursuant to Edwards' own Global Business Practice Standards (the "Code of Conduct");
 - (ii) Conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
 - (iii) Remain informed as to how Edwards conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;
 - (iv) Establish and maintain systematic and accurate records and reports of the business and internal affairs of Edwards and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause

- (v) Maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Edwards' operations would comply with all applicable laws and Edwards' financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;
- (vi) Exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;
- (vii) Refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and
- (viii) Examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.
- 39. Each of the Individual Defendants further owed to Edwards and the shareholders the duty of loyalty requiring that each favor Edwards' interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.
- 40. At all times relevant hereto, the Individual Defendants were the agents of each other and of Edwards and were at all times acting within the course and scope of such agency.

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- 41. Because of their advisory, executive, managerial, and directorial positions with Edwards, each of the Individual Defendants had access to adverse, non-public information about the Company.
- 42. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Edwards.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

- 43. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.
- 44. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty and unjust enrichment.
- 45. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company, purposefully, recklessly, or negligently, to conceal material facts, fail to correct such misrepresentations, and violate applicable laws.
- 46. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants, who are directors of Edwards, was a direct, necessary, and substantial participant in the conspiracy, common enterprise,

and/or common course of conduct complained of herein.

- 47. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted the accomplishment of that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.
- 48. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Edwards and at all times acted within the course and scope of such agency.

EDWARDS' CODE OF CONDUCT

- 49. Edwards' Code of Conduct, titled "Global Business Practice Standards," opens with a letter from Defendant Mussallem to employees stating, in relevant part: "We take pride in conducting our business with honesty, openness and fairness and in accordance with legal standards and the highest ethical principles because it is the right thing to do." Defendant Mussallem further instructs that the Code of Conduct applies to all employees and members of the Board.
- 50. With respect to "Conflicts of Interest," the Code of Conduct states, in part: "We avoid entering into arrangements or agreements that conflict, or appear to conflict, with our responsibilities to Edwards. A conflict of interest can arise when we put our personal interests ahead of Edwards' interests."
- 51. With respect to "Corporate Opportunities," the Code of Conduct provides, in relevant part: "We do not take advantage of Edwards' corporate opportunities for personal profit." The Code of Conduct further provides:

You have an obligation to advance our Company's business interests

when the opportunity arises. Don't take for yourself—or direct to a third-party—an opportunity that you discover through your position or through the use of Company property or information, unless the General Counsel documents that Edwards has no interest in it and that it is appropriate for you to pursue the opportunity. If an employee interested in an opportunity is an executive officer or Board member, the Board of Directors or its designated committee will decide the matter.

52. In a section titled "Inside Information," the Code of Conduct states: We do not trade on or disclose confidential, or "inside information."

It is illegal to buy or sell stock or other securities when aware of inside information about a company that is material and has not been disclosed to the public. It is also illegal to give this information to others so that they can trade. Material information is any news or fact that a reasonable investor could consider important in deciding whether to buy, sell or hold the securities of a company. The materiality of the information must be viewed in light of the certainty and the impact the information could have on Edwards as a whole. Examples include information about:

- Acquisitions or divestitures of businesses, product lines or technologies
- Sales and earnings figures and trends
- Important litigation
- Anticipated product approvals or product approval delays
- Financial forecasts or estimates
- Major supply agreements
- Clinical trial information or data reports

• Commercial product launches

Trading on this information may create an unfair advantage, so if you are in possession of any Edwards material, non-public information, you may not buy or sell Edwards securities or otherwise use the information for personal gain.

* * *

Our executives, Board members and certain other designated individuals ("insiders") are subject to additional requirements to preclear and report their trades. Insiders and any employee with a title of vice president or above are prohibited from holding the Company's securities in a margin account or otherwise pledging the Company's securities as collateral for a loan and hedging the Company's securities, including entering into short-sales, options, puts, calls and sales against the box, as well as derivative transactions including swaps, forwards, futures, collars and exchange funds. Designated insiders are subject to blackout periods and other trade restrictions. Those designated must coordinate all trading activity with the Legal department.

Executive officers and Board members may hold shares in a broker's name only if they provide written notice of this fact and report any changes in these holdings to the General Counsel.

53. In a section titled "Fraud," the Code of Conduct provides, in relevant part:

Preventing and detecting fraud is key to keeping our reputation sound and avoiding costly issues and missed opportunities. Fraud generally involves some form of deception—such as theft or making a false statement—in order to obtain a financial benefit or other advantage. We insist on integrity in all of our work and the work of our partners. Fraud

is prohibited, even if it is meant to benefit Edwards. 1 Be aware of these potential fraud red flags: 2 3 • Misrepresentations about products or services to gain or protect 4 business 5 • Failure to disclose required information 6 In a section titled "Communications with Investors," the Code of 54. 7 Conduct provides, in relevant part: 8 All public disclosures, including reports and documents filed with the 9 U.S. Securities and Exchange Commission, press releases, speeches 10 and other communications must be honest, accurate, timely and 11 representative of the facts. As part of our commitment, we: 12 • Do not make disclosures on a selective basis, but we do disclose 13 material information to the public in compliance with U.S. 14 15 securities laws Ensure that our disclosures are full, fair, timely and 16 understandable 17 • Comply with Company accounting policies and procedures as 18 required and cooperate fully with internal and external auditors 19 EDWARDS' AUDIT COMMITTEE CHARTER 20 Pursuant to Edwards' Audit Committee Charter, the purpose of the 21 55. Audit Committee is to assist the Board in fulfilling its oversight responsibilities 22 relating to the following: 23 integrity of the Corporation's financial statements; 24 25 26 independent auditors; 27 28

independent auditor's qualifications and independence; performance of the Corporation's internal audit function and VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

- Corporation's compliance with legal and regulatory requirements;
- Corporation's disputes and litigation;

- Corporation's investment and hedging activities; and
- Corporation's enterprise-wide risk management practices.
- 56. In a section detailing the Audit Committee's "Key Responsibilities," the Audit Committee Charter provides, in relevant part:

The Committee's job is one of oversight and it recognizes that the Corporation's management is responsible for preparing the Corporation's financial statements and determining that such financial statements are complete and accurate and are in accordance with generally accepted accounting principles, and that the outside auditors are responsible for planning and conducting the audits of those financial statements. Additionally, the Committee recognizes that financial management, including the internal audit staff as well as the outside auditors, have more time, knowledge, expertise and detailed information on the Corporation than do Committee members; consequently, in carrying out its oversight responsibilities, the Committee is not providing any expert or special assurance as to the Corporation's financial statements or any professional certification as to the outside or internal auditor's work.

- 57. With respect to the Audit Committee's responsibilities concerning "Internal Audit," the Audit Committee Charter provides, in relevant part:
 - Review the qualifications and organizational structure of the internal audit function and concur in the appointment, replacement, reassignment or dismissal of the individual responsible for the Corporation's internal audit function, who shall report directly to the

Committee.

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- Review the proposed audit plan of the internal auditor, including the independence and authority of the internal auditor's reporting obligations, the adequacy of internal audit resources and the coordination and completeness of coverage between the internal and independent auditors.
- Receive periodic summaries of findings from completed internal audits and, as appropriate, the status of major audits in process.
 Receive progress reports on the completion of the current year's internal audit plan, including explanations for any significant deviations from the plan.
- 58. With respect to "Risk Management," the Audit Committee Charter states that the Audit Committee shall:
 - Discuss guidelines and policies with respect to risk assessment and risk management, including treasury risks, legal and compliance risks and risks related to information technology, information security, cybersecurity, and the Corporation's enterprise risk management practices, it being understood that it is the job of management to assess and manage the Corporation's exposure to risk.
 - Receive periodic reports on the Corporation's overall risk management process and review significant risks and exposures identified by management, the internal auditors and the independent auditors, including the steps management has taken to monitor and control such risks and exposures.
- 59. With respect to the Audit Committee's responsibilities concerning "Financial Reporting," the Audit Committee Charter states, in relevant part:

- Meet to review and discuss with management and the independent auditor the consolidated financial statements that will be contained in the Corporation's annual and quarterly reports, including reviewing the Corporation's specific disclosures under "Management Discussion and Analysis of Financial Condition and Results of Operations."
- Discuss earnings press releases, as well as financial information and earnings guidance provided to analysts and ratings agencies, paying particular attention to any use of "proforma," or "adjusted" non-GAAP information, it being understood that such discussions may, in the discretion of the Committee, be done generally (i.e., by discussing the types of information to be disclosed and the type of presentation to be made) and that the Committee need not discuss in advance each earnings release or each instance in which the Corporation gives earnings guidance.
 - Discuss with the independent auditor the auditor's judgments about the quality and the acceptability of accounting principles used to prepare the Corporation's consolidated financial statements. Review with management and the independent auditor the impact on the annual financial statements of any significant accounting and financial reporting issues and judgments made in connection with the preparation of the financial statements, any matters arising from the audit of the Corporation's financial statements that are expected to constitute "critical audit matters" as defined by applicable PCAOB auditing standards, as well as recent professional and regulatory pronouncements and any newly adopted or proposed changes in accounting principles that would significantly affect the

Corporation or its consolidated financial statements.

- Review the Corporation's financial reporting processes, based on consultation with management, the independent auditor and internal auditor. Such review shall include consideration of major issues accounting principles financial regarding and statement significant presentations, including any changes in the Corporation's selection or application of accounting principles, and major issues as to the adequacy of the Corporation's internal controls and any special audit steps adopted in light of identified deficiencies.
- Review the adequacy and effectiveness of the Corporation's financial, accounting and disclosure controls with management, the independent auditor and the internal auditor, as appropriate, receiving recommendations for the improvement of such controls and reviewing whether any such previously approved recommendations have been implemented.
- Review annually the effect of off-balance sheet structures, if any, on the Corporation's financial statements.
- 60. As for "Ethical and Legal Compliance," the Audit Committee Charter states that the Audit Committee will, among other things, "assist the Board in establishing and monitoring compliance with the ethical business practice standards of the Corporation," "[r]eview the effectiveness of the system for monitoring compliance with laws and regulations," and "receive reports from the General Counsel or Chief Compliance Officer on the results of management's review of compliance with the Corporation's policies and any investigations by management related to significant fraudulent acts or irregularities."

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SUBSTANTIVE ALLEGATIONS

61. Edwards is a medical technology company specializing in artificial heart valves and hemodynamic monitoring. The Company's TAVR segment manufactures and sells heart valve replacement technologies designed for the minimally-invasive procedures.

The Individual Defendants' False and Misleading Statements

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62. On February 6, 2024, Edwards issued a press release announcing financial results from the fourth quarter and full year fiscal 2023 stating, in part, that "Q4 TAVR sales grew 13 percent; constant currency sales grew 12 percent." Defendant Zovighian was quoted in the release as stating:

significant In 2023, made progress advancing team transformational therapies for patients while delivering strong financial performance. Full year sales increased 12 percent, including impressive growth across each of our four product groups. We exited the year with strong momentum driven by our broad portfolio of innovative therapies. In 2024, we anticipate launching multiple breakthrough technologies globally and advancing important clinical trials as we embark on a new era of structural heart innovation. These breakthroughs, along with significant unmet patient needs, give us confidence in our ability to accelerate growth in 2025 and beyond.

63. The February 6, 2024 press release further detailed the Company's TAVR results, stating, in part:

For the quarter, the company reported global TAVR sales of \$979 million, an increase of 13 percent versus the prior year, or 12 percent on a constant currency basis. Performance was driven by double-digit constant currency growth in the U.S., Europe and Japan. *The company's competitive position was stable globally and local selling*

prices were also stable.²

In the U.S., the company remains pleased with the continued expansion and adoption of the SAPIEN 3 Ultra RESILIA platform. This technology builds on Edwards' leadership in tissue technology and durability by combining advancements in tissue science with the industry leading SAPIEN 3 Ultra valve to offer the only dry storage transcatheter heart valve for U.S. patients today. The company remains confident that the future of TAVR remains strong driven by an increased focus on patient activation, a platform that delivers lifetime management for aortic stenosis patients, advances in new technologies such as RESILIA tissue, as well as indication expansion and increased global adoption.

Looking ahead, the company is pleased with the recently announced CE Mark approval for the SAPIEN 3 Ultra RESILIA platform and plans a disciplined launch in Europe. Long-term, the company continues to anticipate excellent opportunities for growth, as international adoption of TAVR therapy remains quite low.

64. Also on February 6, 2024, the Company hosted an earnings call with analysts and investors to discuss the previously announced financial results. During the call, Defendant Zovighian stated, in relevant part:

We are pleased with our strong 2023 financial performance with full year sales up 12% to \$6 billion, including strong growth across each of our 4 product groups. We invested more than \$1 billion in research and development, and we achieved key strategic milestones, including the introduction of new technologies and indication expansion to ensure

² Emphases added unless otherwise indicated.

sustainable healthy growth in the near, mid and long term. We exited the year with strong momentum with Q4 growth of 13% and TAVR growth of 12%. These results were better than expected, driven by our broad portfolio of innovative therapies.

In 2024, we are well positioned to enter a new era of structural heart innovation. In TAVR, we are strengthening our leadership. We are experiencing strong adoption of our flagship SAPIEN 3 Ultra RESILIA and continuing enrollment in our ALLIANCE pivotal trial for our next-gen TAVR technology, SAPIEN X4.

Now I will provide some additional detail by product group. In TAVR, our full year 2023 global sales of \$3.9 billion increased 10.6% year-over-year. Our U.S. and OUS sales growth rates were similar. In the fourth quarter, our global TAVR sales of 979 million increased 12% year-over-year. Performance was driven by double-digit growth in the U.S., Europe and Japan.

The company's competitive position was stable globally and local selling price were also stable. In the U.S., we remain pleased with the continued expansion and adoption of a SAPIEN 3 Ultra RESILIA platform. This technology builds on Edwards' long-standing leadership in tissue technology and durability by combining advancements in tissue science with the industry-leading SAPIEN 3 Ultra valve.

Developing safe, effective and durable heart valve requires significant long-term commitment, and we are proud to be on 65 years on valve innovation while leveraging the expertise and know-how of more than 2,000 engineers and R&D specialists across the company. We are proud of uninterrupted leadership in structural heart and will continue to

invest vigorously in these platforms. In addition, our scaling of patient activation initiatives, along with next-gen TAVR and additional evidence on asymptomatic and moderate AS patients position us for healthy, sustainable TAVR growth well into the future.

Outside of the U.S., in the fourth quarter, our double-digit growth was comparable with our global TAVR growth, driven by Europe and Japan. Long term, we continue to anticipate excellent opportunities for growth. The international adoption of TAVR therapy remained quite low in many regions. In Europe, Edwards sales growth was driven by the broad-based adoption of our SAPIEN platform. It is encouraging that the growth in Q4 was widespread across all major countries.

Looking ahead, we are pleased with the recently announced CE Mark approval for SAPIEN 3 Ultra RESILIA, and we are planning for a disciplined launch. We were pleased with our sales growth in Japan, and as expected, we grew faster than overall procedural growth. After more than 20 years of rigorous clinical experience and over 1 million patients treated with SAPIEN around the world, our TAVR platform is positioned for continued global leadership and strong sustainable growth.

Given the undertreatment rates, we are confident in the future of TAVR, driven by greater awareness, patient activation, a platform that delivers lifetime management for AS patients, advances in new technologies such as RESILIA as well as indication expansion and increased global adoption.

In TAVR, we will continue to drive global adoption of SAPIEN 3 Ultra RESILIA, present pivotal trial data from early TAVR, studying

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asymptomatic AS patients and enrolling ALLIANCE a pivotal trial studying the next-generation SAPIEN X4.

During the same call, Defendant Wood responded to an analyst's 65. question concerning TAVR market growth going forward, stating, in relevant part:

That's a great question. I think the first thing is we're just going to learn a lot from this trial. There's a lot of unknown questions out there in terms of what percentage of patients are truly asymptomatic when subjected to a stress test? I think how fast do people progress and what happens to people why they're waiting. I think the biggest thing about it is, as we've talked about, and I spent a lot of time at the investor conference, the time from a patient to get diagnosed to treated is just really long. And a lot of that is the interpretation, the guidelines and this overlay of symptoms. And it's all really stand in the gears preventing the patients from moving through. And unfortunately, given the deadliness of the disease, a lot of people never actually make it to therapy.

I think with the early TAVR trial, assuming that it's successful, it will just streamline that process where we can just apply guideline criteria to aortic stenosis, and it won't require this additional evaluation of symptoms and people can just move through. But remember, only about 13% of patients right now with severe aortic stenosis actually get treated. So there's a huge undertreatment right now. We think asymptomatic just adds to that.

66. In response to the same question, Defendant Zovighian added: In addition, Robbie, what I like is our commitment to -- after 20 years of TAVR, we are still in a super committed to bring big evidence. Look at these 2 trials, progress and early TAVR. This is a potential for sure

67. In follow-up to that response, Defendant Wood engaged in the following exchange with a separate analyst concerning, among other things, TAVR and Japan:

Analyst, Morgan Stanley: Amazing. I guess maybe for the first one on TAVR and Japan in general. Do you think you've been taking back some share post trialing. It sounded like you feel very good about the market, and you were taking back some share on that side. Just any color you could give there would be great.

Defendant Wood: Sure. I think what happens when new technology comes into Japan just because of the way the certification process works and people having to move through that process, that certainly had an impact for us. I think in Q4, we grew faster than the market. And I think that really relates to some of the trialing ending and people kind of moving back to our platform. But this is sort of something that goes on, but we're very pleased with how we grew in Japan in Q4 and continue to look forward to that market growing because it's a very - it's a much lower penetrated market than places like the U.S. and Europe. So we continue to see that as a long-term growth driver for us.

68. Also during the question-and-answer portion of the February 6, 2024 earnings call, Defendant Zovighian spoke to the future of TAVR, stating, in relevant part, that Defendants "still believe that there is a way for TAVR to grow healthy double digit in the many years to come globally."

69. During another exchange on the same call, one analyst asked, concerning TAVR, on "did you see any results you feel from these field activations and patient activation efforts in Q4? Or is that something that's still to come?" Defendants Ullem, Wood, and Zovighian responded, stating in relevant part:

Defendant Ullem: Matt, I think we saw some benefit from the patient activation initiatives that we have in place. It's tough to isolate those from the other efforts that we have underway to continue to support the growth of TAVR. But no, that's certainly helping drive growth in the fourth quarter and beyond.

Defendant Wood: Just to add on to this, I mean, I think it'd be incorrect to say our patient activation efforts are just starting to pay dividends now. We've been doing patient activation for the last, I don't know, 5 or 6 years through our digital campaigns, through some of our website stuff, some of our patient resources, some of the general cardiology awareness events we do and a number of other things that have been driving this. So I think patient activation has been contributing all the way along the way.

I think what we're talking about now, though, is a much more sophisticated approach and program to really tapping in to these untreated patients that are in the system, but hospitals don't really realize that they're there. And how do we bridge those gaps. And that's really where our activation now is because we know the patients are there. We know they're diagnosed with an echo, but they're not moving. And so it's just a matter of tapping into those patients in the right way and getting the accelerated through the system.

Defendant Zovighian: What's fair to say though is, in the past few years, we have done many pilots, many initiatives. We have extracted so many

learnings. What we are doing right now is scaling. We are scaling and spending. We are spending resources in Q4 last year, this year and the next few years. So you are going to see more and more because we believe there are so many patients in need not receiving a treatment.

- 70. On March 26, 2024, the company filed the 2024 Proxy with the SEC. The 2024 Proxy solicited shareholders to, among other things: (i) reelect Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani to the Board, as well as elect Defendant Davis to the Board for the first time; (ii) approve, on a non-binding advisory basis, the compensation of Edwards's executive officers; and (iii) approve an Amended Long-Term Stock Incentive Plan (the "2024 Amended Stock Plan"), modifying the Company's existing Long-Term Stock Program.
- 71. The 2024 Amended Stock Plan called to, among other things, increase the aggregate number of shares of the Company's common stock available for issuance by an additional 6,900,000 shares and increase the aggregate number of shares of common stock that may be issued as restricted stock and Restricted Stock Unit ("RSU") awards by an additional 2,000,000 shares. The additional 6,900,000 shares represented 1.15% of the Company's outstanding shares as of December 31, 2023. The 2024 Amended Stock Plan also called to extend the Company's ability to grant new awards under the Long-Term Stock Program through February 21, 2034, from the previous expiration date of February 25, 2026.
- 72. With respect to "Risk Oversight," the 2024 Proxy stated, in relevant part:

Effective risk oversight is a priority for our Board. Its role includes understanding the critical risks in the business, including the severity and immediacy of such risks, allocating the responsibilities for risk oversight among the full Board and its committees, evaluating our Company's risk management processes and facilitating open communication between management and our directors.

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While our Board oversees risk management, our Company's management is charged with managing risk and bringing to our Board's attention emerging risks as well as discussing the status of the longterm risks facing our Company. Our strategic planning processes are designed to facilitate the identification and management of such risks and ensure regular communication with our Board and its committees. Our Board, in its full composition and working through its committees, proactively participates in the oversight of management's actions. At each regularly scheduled Board meeting, and at least once per quarter, our Company's management provides the full Board with an analysis and assessment of the key risks facing our Company. The Chairman of the Board and the Chairpersons of our two committees review and approve the agendas for, and information provided in, such meetings, and call for additional meetings or executive sessions of our Board or its committees to discuss risk-related topics as they may, individually or collectively, determine necessary or appropriate. Our Board also regularly engages with outside advisors and experts as it deems appropriate from time to time to evaluate and anticipate current key risk areas and consider strategies to respond. These advisors and experts provide valuable information, including clinicians' perspectives, and best practices, landscape overview, industry trends and peer data in areas such as the global regulatory environment, governance, compensation, global operations and corporate impact, to facilitate our Board's fulsome review and discussion of these risk areas with the

management team, which then informs action and strategy.

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Our Board committees each play a significant role in carrying out our Board's risk oversight function. Our Audit Committee oversees risks related to our Company's financial statements and the financial reporting process, including our internal control over financial reporting, disclosure controls and procedures and accounting matters. In its oversight of our controls and procedures, our Audit Committee may receive reports or recommendations for the improvement of such controls and procedures from our Senior Vice President of Global Internal Audit, other members of management or our Company's independent auditor to help mitigate risk. Our Audit Committee may engage such other advisors as it deems appropriate to assess our Company's management of risk. It also regularly reviews our enterprise-wide risks and related management processes, focusing on manufacturing processes and supplier quality, product development processes and systems, continuity of our operations and regulatory compliance. In addition, our Audit Committee regularly reviews reports from our Corporate Vice President and General Counsel on certain legal risks, and also reviews treasury risks (insurance, credit, debt, currency risk and hedging programs) and risks related to other management functions. Senior leaders of our Company present at least twice a year, and sometimes more frequently as applicable, on information infrastructure and cybersecurity technology information security risks. Our Audit Committee further regularly reviews the corporate compliance program to assess its effectiveness at identifying and managing compliance risks, including but not limited to mechanisms and channels for compliance concerns to be reported. It periodically receives reports on, and discusses, the risk management and escalation process, and reviews significant risks and exposures identified by management, the internal auditors, or the independent public accountants, including the steps management has taken to monitor and control such risks and exposures.

* * *

Each committee reports regularly to the full Board on its activities. Our Board believes its choice of leadership structure as described under "Board Leadership Structure" above, facilitates effective risk oversight by our Board by ensuring independent director review by our Lead Independent Director (and following the Annual Meeting, by our independent Chairman of the Board), and working through our independent Board committees, of key risk areas and management's risk management actions and priorities.

73. In a section detailing the Company's "Corporate Governance Guidelines," the 2024 Proxy provided, in relevant part:

Our Board has adopted a set of Corporate Governance Guidelines to assist our Board and its committees in performing their duties and serving the best interests of our Company and its stockholders. The Corporate Governance Guidelines cover topics including, but not limited to, director selection and qualification, director responsibilities and operation of our Board, director access to management and independent advisors, director compensation, director orientation and continuing education, risk oversight, succession planning, recoupment of incentive-based compensation and the annual evaluations of our Board. Our Corporate Governance Guidelines are available on our

- 74. In a section detailing the functions and responsibilities of the Audit Committee, the 2024 Proxy stated that the Audit Committee "assists our Board in establishing and monitoring ethics and compliance with the Global Business Practice Standards [the Code of Conduct] of our Company."
- 75. The 2024 Proxy was solicited by Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Mussallem, Marsh, Sequeira, and Valeriani. As a result, shareholders voted to, *inter alia*, reelect Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani, as well as elect Defendant Davis to the Board for the first time, and approve the 2024 Amended Stock Plan.
- 76. The above-detailed statements contained in the 2024 Proxy were false and misleading. Specifically, the 2024 Proxy failed to disclose that the Individual Defendants had created the false impression that they had reliable information regarding the Company's projected revenue and anticipated growth, while further failing to disclose: (i) risk from seasonality and macroeconomic fluctuations were underplayed; (ii) the Individual Defendants' model for growth relied too heavily, or otherwise overstated, hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies; (iii) as a result, there was a significant risk that TAVR's growth would decelerate; and (iv) the Company lacked internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.
- 77. Additionally, the 2024 Proxy failed to disclose that: (1) though the Company claimed its officers and directors adhered to the Code of Conduct, the Individual Defendants violated these policies either without waivers or without such waivers being disclosed; and (2) contrary to the 2024 Proxy Statement's

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descriptions of the Board's and its committees' risk oversight functions, the Board and its committees were not adequately exercising these functions and were causing or permitting the Company to issue false and misleading statements.

Document 1

- 78. As a result of the shareholders approving the 2024 Amended Stock Plan, an additional 6,900,000 shares were made available for disbursement. Additionally, the term of the 2024 Amended Stock Plan was extended from expiring on February 25, 2026, through February 21, 2034. As such, the Individual Defendants continue to receive material personal benefits in the form of stock awards and will continue to receive material personal benefits in the form of stock awards pursuant to the 2024 Amended Stock Plan in the future.
- 79. On April 25, 2024, the Company issued a press release announcing financial results for the first quarter 2024, stating that "Q1 TAVR sales grew 6%; constant currency sales grew 8% adjusted for billing days."
- 80. Also on April 25, 2024, the Company hosted an earnings call with analysts and investors to discuss first quarter 2024 financial results. During the call, Defendant Zovighian spoke to TAVR's slow growth during the quarter, stating:

Now, I will provide some additional detail on Q1 results, by product group. In TAVR, first quarter global sales of \$1 billion increased 8%, year-over-year, when adjusted for billing days. Q1 marked the first quarter that Edwards TAVR sales exceeded \$1 billion, an exciting milestone for our team and a testament to clinicians' confidence in our leading technology. Performance was driven by growth in the U.S. and Japan, Edward's global competitive position, and selling prices were both stable.

In the U.S., our year-over-year first quarter TAVR sales growth rate was higher than our global constant currency growth rate. We estimate total procedure growth was comparable. Procedure volumes increased, as the quarter progressed.

We remain pleased with the continued performance of our best-in-class TAVR platform, SAPIEN 3 Ultra RESILIA, which builds on Edwards long-standing leadership in tissue technology and durability. This innovative technology now makes up the majority of our sales in the U.S. This platform is supported by the robust real world data for more than 10,000 patients in the TVT Registry that demonstrated excellent outcomes, across hundreds of centers.

Outside of the U.S., in the first quarter, our constant currency TAVR sales growth was slightly below our global TAVR growth. Strong growth in Japan and the rest of the world was partially offset by slower-than-expected growth in Europe. In Europe, our results were softer than expected in Q1. But we expect full year 2024 performance to normalize. We are actively preparing for the launch of SAPIEN 3 Ultra RESILIA in Europe, and we anticipate introducing the technology into the European market in Q2.

In Japan, we continue to see strong TAVR adoption driven by SAPIEN 3 Ultra RESILIA. We believe AS remains a significantly undertreated disease among the substantial elderly population and continue to focus on expanding the ability of an evidence supporting this therapy.

In closing, we are confident that Edwards is positioned for healthy and sustainable TAVR growth well into the future, driven by our development of differentiated TAVR technology, our deep commitment to advancing patient care through high-quality clinical evidence and our investment in patient activation initiatives.

Importantly, we are proud of our groundbreaking research into the

treatment of AS through our early TAVR and PROGRESS trial, which could fundamentally change how AS patients are treated. We remain confident in our full year TAVR sales growth of 8% to 10%. We expect higher year-over-year second half growth rate than in the first and second quarter.

Document 1

81. During a question-and-answer portion of the April 25, 2024 earnings call, one analyst asked "how are you thinking about TAVR growth for the rest of the year? And do you feel like the U.S. has finally recovered after some of the setbacks you saw during the disruptive years of COVID?" In response, Defendants Zovighian and Wood stated, in relevant part:

Defendant Zovighian: Thanks, Robbie. Let me start, and again, I will ask Larry to add some insights here. So when we put together a guidance for the year, the guidance 8% to 10%, we knew that the growth will ramp throughout the year and that Q1 will be our lowest growth quarter. So we feel we are confident about our 8% to 10%. We feel confident about what's happening in the U.S. Share and price are stable. So we feel good about all of that....

Defendant Wood: Yes. I don't have a lot to add. We saw good progression throughout the quarter. It's always a little slow in January as we come out of the break, but we are pleased with how the quarter went overall. And we remain excited about the year. We have a lot of activities on patient activation. We have a huge data set coming out of TCT that I think all of us are going to be excited to see what that say, what those data say and how they inform the field. And so I continue to believe we have a long runway long term with TAVR and it is good to see the U.S. kind of out COVID, I think, finally in the rearview mirror, and we can just focus on accelerating patient care.

82. Also on the call, another analyst asked "on TAVR again, curious why European growth was slower than expected. And then on the billing days, were those U.S. or OUS and those come back in any quarter?" Defendant Wood responded, stating:

Yes, thanks. Yes, overall, we felt good about the quarter, and we just talked about the U.S. We saw a lot of strength in Japan, but Europe was -- it grew year-over-year and it grew sequentially, and we lost a couple of billing days. But even with that, we were a little bit disappointed with our overall growth in Europe. We saw some pretty aggressive pricing from competitors that I think led to some trialing. But we're really excited that we're launching S3UR that actually starts this month, and we're excited to bring that technology to Europe, and we expect these to normalize through the course of the year.

83. In a follow-up question from the same analyst concerning the impact on TAVR growth from the Company's relationship with digital healthcare company Egnite, Defendants Wood and Zovighian responded:

Defendant Wood: Yes. We have a lot of patient activation activities where there's a lot of work that we do. We have multiple fronts, and Egnite is just one part of our strategy there. But we're excited about what these technologies can do. And there are so many patients, if you look at the [indiscernible] publication, and I know he's spoken to you guys before, there's just a lot of patients upstream that aren't moving through the system at the speed in which they should. And I think there's a patient identification aspect, there's a referral aspect.

So we have multiple work streams working on this. But I think the appreciation and understanding for the undertreatment of aortic stenosis is growing. And I think as that grows and people start to understand the

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magnitude of the problem, I think it gives more opportunity for our patient activation strategy to take hold.

Defendant Zovighian: And maybe in addition, Larry, I'm very proud about what we are doing. We are the only one basically having a deep commitment to advancing science for AS patients through the progress and early TAVR trial. So this is truly our commitment, but we feel that there is a ton of potential. These patients are underdiagnosed [indiscernible], and we are committed to offer treatment for these patients. So as a company, very proud about how we do all of this.

84. Also on the call, Defendant Wood engaged in the following exchange: Analyst, Wells Fargo Securities, LLC: I just wanted on TAVR, I wanted to confirm, Bernard, that Q2 TAVR growth will be better than Q1, in response to Robbie's question. And why do you expect TAVR growth to accelerate in the second half? And how are you guys factoring in the SMART trial results? And I have one follow-up.

Defendant Wood: Yes. Yes, we do expect to have procedures to ramp. That's always been a part of our plan, and so we continue to expect that to happen. And I think it's a lot of things, Larry, I think it's a lot of our patient activation work. But it's also just the market continues to improve, and we're very pleased where we finished Q4 last year. We were happy with the ramp in Q1. So I think we do expect to see an increase in Q2 over Q1. But even with that, we expect the second half to have a higher growth rate than the first half. So I think that that's good.

In response to an analyst' question concerning TAVR and 85. transcatheter valve growth, the "the launch of EVOQUE and the activity that, that drives in some of your major centers" and "managing those activity levels

[indiscernible] centers versus the continuing volumes that they perform in TAVR[,]" Defendant Zovighian stated: "It is fair to say that so far, we have not faced a big challenge in terms of center, having a lack of capacity to be able to treat the patients, whether TAVR patients or EVOQUE patients."

- 86. Also during the question-and-answer portion of the April 25, 2024 call, Defendant Ullem engaged in the following exchange:
 - Analyst, RBC Capital Markets: Sorry about earlier. It just sounds like U.S. TAVR growth was high single digits. Is that fair? Was it about 10%? And other drivers that can get you to consistent double-digit growth in the foreseeable future? Just what's your confidence there? Defendant Ullem: Yes. I'll take the first part of that about U.S. TAVR growth. We try not to be too specific about breaking down every region. But what we can say is that TAVR in the U.S. grew faster than our global underlying growth rate for TAVR in the first quarter. Larry, do you want to talk about the other pieces?
- 87. Defendant Zovighian closed the April 25, 2024 call stating that "TAVR, for sure, it is the largest business for us. It's still our #1 focus. TAVR has a lot of growth potential."
- 88. On June 5, 2024, Defendant Ullem presented at the Jefferies 2024 Global Healthcare Conference on behalf of the Company. During an interview at the conference, Defendant Ullem discussed TAVR's impact on the Company's guidance and outlook for fiscal year 2024, stating in relevant part:
 - Senior Analyst, Jefferies LLC: So let's start with TAVR. Could you talk a little bit about the TAVR trends in Q1? I guess you grew a little over 6%, about 7%. And talked about some trialing in Europe and some pricing pressure there.
 - So I guess, could you give us an overview on what's happening, if

there's any update in Q2? And then overall, how do you expect the TAVR market to grow and your growth to be within that?

Defendant Ullem: Yes. So yes, TAVR, we started out in the first quarter with lower year-over-year growth rate than we expect for the full year. Our guidance for TAVR for the year is 8% to 10%. We always knew that the first half of the year was going to be a lower year-over-year growth environment than the second half of the year. That's been our plan, and we saw that in the first quarter again.

Just breaking it down between the 4 areas of the world where we focus our attention, U.S. grew faster than the OUS business in the first quarter. Japan was our fastest big growing region in the first quarter. In Japan, we saw some competitive pressure last year that abated in the second half of last year, and we're back to more of a normalized growth curve in Japan. In Europe, we were surprised a little bit in the first quarter by some of the competitive trialing that we saw. We expect the European environment though to normalize as we get later into 2024. And then the Rest of World where, today, we're in TAVR in over 60 countries. And so there are big growth opportunities in other areas of the world, and that's been a pretty exciting area for us in 2024, and we think it will be in '25 and beyond.

Overall, the business is performing well. There's still an environment now where around 13% of patients who have aortic stenosis, severe aortic stenosis get treated today. And it's a remarkably low treatment rate, especially relative to other diseases with a high mortality rate like severe aortic stenosis, and *it gives us confidence that we should keep investing in this opportunity*.

In fact, we just finished enrollment in an important clinical trial

studying aortic stenosis in patients who just have a moderate form of the disease, where it has not progressed yet to severe. And we think there's a real opportunity to help patients who need earlier intervention to get their valve replaced and today are not on indication to do so with TAVR.

There's another trial that's actually reading out later this year at the TCT Conference, studying patients who have severe aortic stenosis without symptoms. And if the trial shows what we think it will, it will be an important opportunity to make this therapy available to patients who have this deadly disease, but who did not get screened for care because they don't have symptoms today.

So those are some of the factors that are underlying our current performance and what we think are going to benefit our longer-term growth trends as well.

89. The statements detailed above were materially false and misleading when made because they failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Individual Defendants created the false impression that they had reliable information regarding the Company's projected revenue and anticipated growth, while failing to disclose: (i) risk from seasonality and macroeconomic fluctuations were underplayed; (ii) the Individual Defendants' model for growth relied too heavily, or otherwise overstated, hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies; (iii) as a result, there was a significant risk that TAVR's growth would decelerate; and (iv) the Company lacked internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.

The Truth Emerges

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90. On July 24, 2024, Edwards issued a press release discussing financial results for the second quarter 2024, lowering TAVR guidance to a range of 5 to 7% from 8 to 10s%. Defendant Zovighian was quoted in the release as stating: "Second quarter total company sales growth of 8 percent reflected strong contributions from our rapidly growing TMTT [Transcatheter Mitral and Tricuspid Therapies] product group, *offset by lower-than-expected growth in TAVR*." In relevant part, the press release stated:

Highlights and Outlook

- Q2 sales grew 7%; constant currency sales grew 8%
- Q2 TAVR sales grew 5%; constant currency sales grew 6%
- Q2 TMTT sales grew 75%; increasing contribution to Edwards' growth
- Q2 EPS of \$0.61; adjusted1 EPS of \$0.70
- Significant TAVR and TMTT clinical evidence to be presented at TCT in October 2024
- Positive EVOQUE introduction with excellent patient outcomes;
 NCD process on track
- Critical Care sale expected to close late Q3 2024
- Expect full-year 2024 Edwards sales growth of 8 to 10%;
 lowering TAVR guidance to 5 to 7% from 8 to 10%; increasing
 TMTT guidance to the higher end of \$320 to \$340 million

* * *

Transcatheter Aortic Valve Replacement (TAVR)

In the second quarter, the company reported TAVR sales of \$1.0 billion, which grew 5%, or 6% on a constant currency basis. Edwards' competitive position did not meaningfully change globally, although

the company experienced some regional pressures, and pricing was maintained.

Edwards remains pleased with the performance of its SAPIEN 3 Ultra RESILIA platform, which is the leading platform in the U.S. and Japan. In the second quarter, Edwards began the introduction of the SAPIEN 3 Ultra RESILIA valve in Europe. The RESILIA tissue's anticalcification technology is designed to address one of the primary causes of reintervention following heart valve replacement and provides the potential to extend the durability of the valve.

91. During an earnings call held with analysts and investors the same day, Defendant Zovighian highlighted that TAVR grew significantly more slowly than anticipated, stating, in relevant part:

In the U.S., our year-over-year second quarter TAVR sales growth was slightly below our global constant currency growth rate. We believe our U.S. competitive position was largely unchanged. Second quarter U.S. TAVR sales grew slower than expected. The continued growth and expansion of structural heart therapies, including newly approved tricuspid therapies and other fast-growing structural heart therapies put pressure on hospital workflows, which impacted TAVR. These pressures were also observed in the recent spike in emergent TAVR cases as reflected in claims data as centers adopt these new therapies, and they become part of their standard processes, we expect this will stabilize.

* * *

In closing, we now anticipate second half TAVR sales growth similar to the first half year-over-year growth rate, 5% to 7% full year growth rate versus previously guidance of 8% to 10%. This equates to full year

global TAVR sales of \$4 billion to \$4.2 billion.

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92. Defendant Zogihian also addressed the Company's recent acquisitions, stating, in relevant part:

Earlier this month, we announced the acquisition of Innovalve. Innovalve early-stage technology will add to a growing pipeline of innovative therapy in TMTT, and we expect to close the acquisition later this year. We further expect that Innovalve technology, combined with Edwards expertise in mitral disease will enhance the company TMVR technologies to address large unmet structural heart patient needs and support sustainable long-term growth.

* *

Turning down to the strategic acquisition of JenaValve and Endotronix. These acquisitions provide an expanded opportunity in new therapeutic areas to address the unmet needs of AR and heart failure patients around the world. Furthermore, the acquisition reflects our deep commitment to advancing patient care through our unique strategy and reinforce our confidence in Edwards sustainable long-term growth. Starting with JenaValve, a pioneer in the transcatheter treatment of AR, a deadly disease that impacts more than 100,000 patients in the U.S. alone and is largely untreated today. Edwards anticipate U.S. FDA approval of JenaValve Trilogy Heart Valve System in late 2025, which will represent the first approved therapy for patients suffering from AR. Edwards will invest to accelerate development of this novel technology to enable earlier patient access. As the pioneers in valve innovation, we believe we are best positioned to lead this next frontier of aortic valve disease treatment. We expect this to be the beginning of a long-term iterative strategy similar to TAVR.

Turning to Endotronix. Edwards made its first investment in the company in 2016. So we are very familiar with the technology, the opportunity and the employees, many structural heart patients Edwards serve today also suffer from heart failure with a limited options. This acquisition will expand Edwards Structural Heart portfolio into a new therapeutic area to address the large unmet needs of patients suffering from heart failure, which we believe has a significant long-term growth opportunity.

Last month, Endotronix received FDA approval for Cordella, an implantable pulmonary artery pressure sensor that directly measure the leading indicator of congestion, following the publication of the successful U.S. pivotal trial. We are pleased to enter the structural heart therapeutic area with innovation, world-class science and clinical evidence to provide access to life-saving technologies for patients around the world. We anticipate this investment will strengthen its leadership in structural heart innovation and represent long-term growth opportunities. Minimal revenue contribution from JenaValve and Endotronix is expected to begin late in 2025.

93. During a question-and-answer portion of the call, Defendants Wood and Zovighian engaged in the following exchange with an analyst concerning the TAVR setbacks:

Analyst, JP Morgan Chase: Two for me. Maybe first, you talked about it in the script, but I was hoping you could give a little more. TAVR has clearly come in below your initial expectations for the year. The guidance has moved down, the U.S. is slowing, OUS is facing pressure. We saw two of your smaller competitors, but still competitors see pretty nice growth sequentially and year-over-year so their TAVR is taking

more in Europe and outside the U.S., Japan. How are you thinking just about the underlying growth rate of the TAVR market? And I appreciate it's a huge opportunity, and it's still a lot to conquer in the future. But in, let's call it, the short to medium term, how are you thinking about the overall market growth? And is there anything you can do to help accelerate it?

Defendant Wood: Thanks, Robbie. Well, obviously, we expected growth rate to be higher in Q2 than it was. We had a slow start in Q1, but we were exiting March, and we felt good about where we were. So this did come as a surprise. I think when we reflect back on it and we look more deeply at it, you have to think about all the things that have shown up that are going to the same structural heart team at all of these hospitals. We're seeing rapid growth in mitral repair. We're seeing a lot of growth in other procedures. And we had 2 new therapy approvals recently in the tricuspid space.

I think a little bit we looked at the procedure volumes and the hospitals have shown a pretty good job of being able to handle these things. We probably underestimated the burden of even starting these new programs, even preparing to start these new programs because you have to screen the patients early on, there's a lot of learning, screen failures, all of those things. And I think it's just taxing the teams.

Now in terms of things we can do to help, there are certainly things we can do to help. We can do a lot of imaging workups and take some of the load off the team. We can do device prep. We can come in with our benchmark program and teach them efficiencies and do those things. But once the program has been optimized, that it really does come down to the hospital to add another team or add additional days

and do those sorts of things. So there are some things we can do, but we can't do everything.

I think the other thing is, I think, highlighting this for the clinicians. And we're very confident. This isn't some slowdown because there's a lack of patients. We didn't see any of the fundamentals change in terms of new data that was concerning or any of these things. I think it's just a matter of the workflow right now. And we need to be able to engage with hospitals, but two important things we saw is we saw an increase in time from CT to procedure, which indicates patients are waiting longer.

And the other thing that we saw was a sharp increase in the number of cases being coded as emergent versus routine. And I think that speaks to these patients waiting in the queue as these workflow issues sort out. So I think hospitals will certainly do that in time. These patients don't wait well, and we know that there's a lot of them, but we're going to have to continue to work through that with the hospitals. Defendant Zovighian: So let me add on what Larry said. To be fair, we are contributing a little bit on this pressure. At the same time, we are benefiting. If you look at the TMTT growth in the quarter, so we are contributing and benefiting at the same time.

Now a big picture. We have seen this picture in the past, don't you think we have similar hospital facing like more to do, more technology to adopt, to be trained on new technologies and they are very good at scaling, they are very good at learning, they are very good at adapting, they are in their workflows in the cath lab. So we believe it is temporary. And we are -- Daveen also with this team are with Larry partnering on this one. So we are fully focusing on this one, helping in the hospital.

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Defendant Ullem: Yes. We're -- I mean, it's pretty straightforward, which is we're baking into it, similar market conditions the year-over-year calculation is pretty similar. Fourth quarter comp gets a little bit tougher, but we think that all things considered that 5% on the low end, 7% on the high end, captures the likely scenario for the second half combined with the first half that we've already reported.

Defendant Zovighian: We believe, to add in on that, what we believe early TAVR at TCT. It will be already almost the end of a quarter, Robbie, so TCT in late October. So we believe it will have a very minimal impact in Q4. So it is why we didn't want to take too much risk here.

95. Asked specifically about previous guidance of between 8% to 10% for TAVR acceleration, Defendant Wood responded:

Analyst, BofA Securities: I wanted to go back and circle back on Robbie's question on TAVR. It feels like there's a little bit more of a change here. Just 3 months ago, you thought TAVR was going to accelerate over the course of the year. I thought the 8% to 10% at the

beginning of the year was supposed to be a conservative guide. So I just want to understand like -- I hear what you're saying on TMTT, but that's a small number of fractions versus the overall TAVR centers. So I don't know if there's anything else that you'd kind of call out or kind of what surprised you on the TAVR line. I know there was some of the European stuff and competition there that you called out last quarter. Just understanding kind of the full change and why you got the initial TAVR guide wrong at the start of this year?

Defendant Wood: Yes. Thanks, Travis. Yes, when we exited Q1, we

Defendant Wood: Yes. Thanks, Travis. Yes, when we exited Q1, we felt we were on a good ramp and we thought we were on a good pace, and that's why we reiterated guidance and we felt good about it. And we just didn't see that play out in Q2 the way that we anticipated. And by no means do I mean to say this is all Daveen's fault and it's all EVOQUE because that's not accurate or fair when you look at the number of procedures.

I think it's the cumulative impact of all the things that have hit the structural heart teams over the last year. And it's one of those things. You can always increase a little capacity, work a little harder, increase a little capacity, work a little bit harder. But then at some point, you reach a breakpoint when it's simply too much. And the heaviest lift for centers is starting a program. And it's not just the procedure volume. It's all that screening and all of the case reviews and all the interaction that just consumes a lot of resources and a lot of time. And the training, you don't have to go to training and observed cases in many cases and all of those sorts of things. And so I think it's just the cumulative impact of those things that happen over time. And we did see the slowdown more acutely in large centers and small centers, which fits a

little bit of the model as well in terms of the centers that are most likely to be looking to start these new programs and are competitive about that.

And again, I said it earlier, but we did see a spike in emergent cases over routine cases. And I think that fits what we're saying as well. But that's not going to be sustainable for people. Emergent cases have more complications. They don't have as good of patient outcomes and people will have longer length of stay, and that's going to adversely impact patients and the hospitals themselves. So I think people will have to adjust it over time. And we're going to have to work closely with them to help them do that.

96. Also during the call, Defendants Wood and Zovighian responded to an analyst's question concerning, among other things, timeframes for adjustments:

Analyst, Jefferies LLC: I guess I wanted to follow up on some of your U.S. TAVR commentary and the workflow angle because I'd like to understand better why you think it's showing up so acutely now, I guess, given you're still in a limited rollout of EVOQUE, is this an issue that's been matriculating for a while, and we're just seeing it more now? And could you help us understand your history there, you talked about the impact on coronary. How long do you think it will take for the hospital to adjust? Is this a 1 quarter or 3-quarter issue? Does it take years? What kind of time frame would you put on them adjusting to accommodate the additional workflows?

Defendant Wood: Yes. Thanks, Matt. The thing that I would say is, I guess, if I were to draw an analogy, if you had a factory and you saw demand for your product going up, you can always add a little more hours and you always have a little bit of excess capacity and you can

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adjust to those things. I think there is just a point in time where you hit a wall and it's harder to do those things. And I think that's a little bit of what we saw here. It's the cumulative effect of all of these things that have played out over time.

If you look at total cath lab procedures for the structural heart team in the last 3 years, it's probably close to double during that period of time, which is a lot of growth that these teams are having to absorb and they're having to adapt to. And I think it will take time. And again, when you're starting these new programs on these new therapies, that's the heaviest lift part of it. And again, I think this gets corrected over time, and we'll work closely with the hospitals to do that. But we reflected that in our guidance and just wanted to be realistic and not be toned after what's happened. But the same thing I'll tell you is none of us are happy with the growth rates. None of us are happy adjusting guidance, and we're going to be working as hard as we can to do everything we can to restore the growth to where we think it should be.

Defendant Zovighian: And we are not happy as a company. The patients are not happy, the physicians are not happy, the hospitals are not happy. So we are all fully aligned about it is a problem, we need to solve it. So it is why also we are confident here.

97. On this news, the price of Edwards' common stock dropped over 31%, from a close of \$86.95 per share on July 25, 2024, to close at \$59.70 per share on July 26, 2024.

Harm to the Company

As a direct and proximate result of the Individual Defendants' 98. misconduct, Edwards has lost and expended, and will lose and expend, millions of dollars.

- 99. Such expenditures include, but are not limited to, the legal fees associated with the Securities Class Action filed against the Company and Defendants Zovighian, Ullem, and Wood, and amounts paid to outside lawyers, accountants, and investigators in connection therewith.
- 100. Such expenditures also include, but are not limited to, significant compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.
- 101. Furthermore, the Securities Class Action has exposed the Company to massive class-wide liability.
- 102. Additionally, during the Relevant Period, the Individual Defendants caused the Company to initiate repurchases of its common stock that substantially damaged the Company.
- 103. As set forth in the Company's quarterly report filed on Form 10-Q with the SEC on July 31, 2024, the Company engaged in the following share repurchases during the three-month period ended June 30, 2024:
 - (i) Between April 1, 2024, and April 30, 2024, the Company repurchased 1,396,161 shares of its own common stock at an average price per share of \$86.72, or a total cost of approximately \$121,075,082;
 - (ii) Between May 1, 2024 and May 31, 2024, the Company repurchased 333,496 shares of its own common stock at an average price per share of approximately \$86.72 per share, for a total cost to the Company of approximately \$28,920,773.
- 104. As set forth in the Company's quarterly report filed on Form 10-Q with the SEC on November 6, 2024, the Company engaged in the following share repurchases during the three-month period ended September 30, 2024:
 - (i) Between July 1, 2024 and July 31, 2024, the Company

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repurchased 444,999 shares of its own common stock at an average price per share of approximately \$62.91, for a total cost to the Company of approximately \$27,994,887.

- 105. In total, From April 2024 through July 2024, the Company spent an aggregate amount of approximately \$178 million to repurchase approximately 2,174,656 shares of its own common stock at artificially inflated prices.
- 106. As the Company's stock was actually worth only \$59.70 per share, the price at closing on July 25, 2024, the Company overpaid for repurchases of its own stock by approximately \$48.2 million in total, during the Relevant Period.

Insider Sales During the Relevant Period

- 107. During the Relevant Period, while the Company's stock price was artificially inflated and before the scheme was exposed, Defendants Zovighian, Ullem, Gallahue, Heisz, and Mussallem sold substantial portions of Company common stock. These insider sales, made with knowledge of material nonpublic information before the material misstatements and omissions were exposed, demonstrate their motive in facilitating and participating in the scheme.
- 108. On May 30, 2024, during the Relevant Period while Edwards' stock price was artificially inflated, Defendant Zovighian, sold 8,617 shares of the Company's common stock for proceeds of \$755,538.
- 109. During the Relevant Period while Edwards' stock price was artificially inflated, Defendant Ullem sold a total of 33,010 shares of the Company's common stock for total proceeds of approximately \$2.9 million. These sales included:
 - (i) February 29, 2024 - sold 7,255 shares for proceeds of \$620,926;
 - (ii) April 1, 2024 – sold 7,255 shares for proceeds of \$690,371;
 - April 30, 2024 sold 7,250 shares for proceeds of \$624,007; (iii)

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- (v) June 20, 2024 sold 5,625 shares for proceeds of \$493,818.
- 110. On February 23, 2024, during the Relevant Period while Edwards' stock price was artificially inflated, Defendant Gallahue, sold 3,058 shares of the Company's common stock for proceeds of \$267,911.
- 111. On February 8, 2024, during the Relevant Period while Edwards' stock price was artificially inflated, Defendant Heisz, sold 7,056 shares of the Company's common stock for proceeds of \$609,991.
- 112. During the Relevant Period while Edwards' stock price was artificially inflated, Defendant Mussallem sold a total of 88,050 shares of the Company's common stock for total proceeds of approximately \$7.8 million. These sales included:
 - (i) March 4, 2024 sold 29,350 shares for proceeds of \$2,542,590;
 - (ii) April 4, 2024 sold 29,350 shares for proceeds of \$2,730,665; and
 - (iii) May 2, 2024 sold 29,350 shares for proceeds of \$2,489,026.
- 113. In total, during the Relevant Period, these five Individual Defendants' lucrative insider sales netted proceeds of approximately \$12.3 million.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

- 114. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breach of fiduciary duties by the Individual Defendants.
- 115. Edwards is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.
 - 116. Plaintiff is a current shareholder of Edwards and was a continuous

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- shareholder of the Company during the period of the Individual Defendants' wrongdoing alleged herein. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.
- 117. A pre-suit demand on the Board of Edwards is futile and, therefore, excused. At the time this action was commenced, the nine-member Board was comprised of Defendants Valeriani, Zovighian, Davis, Gallahue, Heisz, LaViolette, Lorange, and Sequeira (the "Director Defendants") as well as nonparty David T. Feinberg. Accordingly, Plaintiff is only required to show that five Directors cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. As set forth below, all of the Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action, including because they face a substantial likelihood of liability, and so demand on the Board to institute this action is not necessary because such a demand would have been a futile act.
- The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.
- 119. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.
- 120. Moreover, the Director Defendants willfully ignored, or recklessly failed to inform themselves of, the obvious problems with the Company's internal controls, practices, and procedures and failed to make a good faith effort to correct the problems or prevent their recurrence.

- 121. Defendant Zovighian serves as the Company's CEO, is not disinterested or independent, and is therefore incapable of considering a demand. Thus, the Company admits that Defendant Zovighian is a non-independent director.
- 122. Furthermore, Defendant Zovighian is not disinterested or independent because he is named as a defendant, and faces significant personal liability, in the Securities Class Action based on substantially the same wrongdoing as alleged herein, specifically issuing materially false and misleading statements during the Relevant Period.
- 123. Defendants Heisz, Gallahue, and Sequeira serve or served on the Company's Audit Committee during the Relevant Period (the "Audit Defendants") and, pursuant to the Audit Committee Charter, were specifically charged with the responsibility to assist the Board in fulfilling its oversight responsibilities related to, *inter alia*, financial accounting and reporting, the underlying internal controls and procedures over financial reporting, and the audits of the financial statements. At all relevant times, however, the Audit Defendants breached their fiduciary duty to the Company by failing to prevent, correct, or inform the Board of the issuance of material misstatements and omissions regarding the Company's business and the adequacy of its internal controls as alleged above. Therefore, the Audit Defendants cannot independently consider any demand to sue themselves for breaching their fiduciary duties to the Company, as that would expose them to substantial liability and threaten their livelihoods.
- 124. The Director Defendants, as members of the Board, were and are subject to the Company's Code of Conduct. The Code of Conduct goes well beyond the basic fiduciary duties required by applicable laws, rules, and regulations, requiring the Directors to also adhere to the Company's standards of business conduct. The Director Defendants violated the Code of Conduct because

- 125. All of the Board's current members derive substantial revenue from the Company, control the Company, and are indebted to each other. These conflicts of interest have precluded the Board's current members from calling into question the Director Defendants' conduct.
- 126. Moreover, none of the Director Defendants have taken remedial action to redress the conduct alleged herein.
- above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the directors can claim exculpation from their violations of duty pursuant to the Company's charter. As a majority of the directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein. They cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.
- 128. Additionally, Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani solicited the 2024 Proxy. As a result, these Director Defendants, as well as Defendant Davis, were elected or reelected to the Board, allowing them to continue breaching their fiduciary duties to the Company.
- 129. Furthermore, Individual Defendants Zovighian, Ullem, Gallahue, Heisz, and Mussallem have received material personal benefits from their insider sales as a result of the Individual Defendants' false and misleading statements

- 130. The acts complained of herein constitute violations of fiduciary duties owed by Edwards' officers and directors, and these acts are incapable of ratification.
- 131. Thus, for all of the reasons set forth above, the Director Defendants are unable to consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

COUNT I

Against the Individual Defendants for Violations of § 14(a) of the Exchange Act

- 132. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 133. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 781]."
- 134. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9.

- 136. The Individual Defendants, individually and in concert, disseminated and/or permitted the dissemination of materially false and misleading statements in the 2024 Proxy filed with the SEC. As alleged above, this filing contained materially false and misleading statements concerning the Company's TAVR segment and its internal controls over financial reporting.
- 137. Under the direction and watch of the Director Defendants, the 2024 Proxy failed to disclose, that the Individual Defendants had created the false impression that they had reliable information regarding the Company's projected revenue and anticipated growth, while further failing to disclose: (i) risk from seasonality and macroeconomic fluctuations were underplayed; (ii) the Individual Defendants' model for growth relied too heavily, or otherwise overstated, hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies; (iii) as a result, there was a significant risk that TAVR's growth would decelerate; and (iv) the Company lacked internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.
- 138. Additionally, the 2024 Proxy failed to disclose that: (1) though the Company claimed its officers and directors adhered to the Code of Conduct, the Individual Defendants violated these policies either without waivers or without such waivers being disclosed; and (2) contrary to the 2024 Proxy Statement's descriptions of the Board's and its committees' risk oversight functions, the Board and its committees were not adequately exercising these functions and were causing or permitting the Company to issue false and misleading statements.

- 140. The misrepresentations and omissions in the 2024 Proxy were material to Company stockholders in voting on the matters set forth for stockholder determination in the 2024 Proxy, including but not limited to the reelection of certain Director Defendants and approval of the 2024 Amended Stock Plan. The 2024 Proxy was an essential link in Defendants' insulation from stockholder challenge.
- 141. As a result of the material misstatements and omissions contained in the 2024 Proxy, shareholders voted, inter alia, to reelect Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani, as well as elect Defendant Davis for the first time, to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company, and to approve the 2024 Amended Stock Plan.
- 142. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the 2024 Proxy.

COUNT II

Against the Individual Defendants For Violations of Section 10(b) and Rule 10b-5 of the Exchange Act

- 143. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.
- 144. Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make

- 145. The Individual Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they: (i) employed devices, schemes and artifices to defraud; (ii) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (iii) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated.
- 146. The Individual Defendants acted with scienter because they (i) knew that the public documents and statements issued or disseminated in the name of Edwards were materially false and misleading; (ii) knew that such statements or documents would be issued or disseminated to the investing public; and (iii) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws.
- 147. The Individual Defendants, by virtue of their receipt of information reflecting the true facts of WM, their control over, and/or receipt and/or modification of Edwards' allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Edwards, participated in the fraudulent scheme alleged herein.
- 148. As a result of the foregoing, the market price of Edwards common stock was artificially inflated. In ignorance of the falsity of the statements, stockholders relied on the statements described above and/or the integrity of the market price of Edwards common stock in purchasing Edwards common stock at prices that were artificially inflated as a result of these false and misleading

- 149. As a result of the wrongful conduct alleged herein, the Company has suffered significant damages, including the costs and expenses incurred in defending itself in the Securities Class Action and reputational harm. The Individual Defendants, through their violation of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, have exposed the Company to millions of dollars in potential class-wide damages in the Securities Class Action.
- 150. Additionally, Edwards itself is also one of the largest victims of the unlawful scheme perpetrated upon the Company by the Individual Defendants. With the price of its common stock trading at artificially inflated prices due to the Individual Defendants' misconduct, the Individual Defendants caused the Company to repurchase its own shares at artificially inflated prices, damaging Edwards.
- 151. By virtue of the foregoing, the Individual Defendants have violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

COUNT III

Against the Individual Defendants For Breach of Fiduciary Duty

- 152. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 153. The Individual Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.
- 154. The Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.
 - 155. The Individual Defendants engaged in a sustained and systematic

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failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by failing to implement and monitor adequate internal controls over the Company's financial reporting and, as a consequence, issuing or permitting the issuance of materially false and misleading statements in the Company's SEC filings and other public disclosures. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

- 156. Specifically, the Individual Defendants created the false impression that they had reliable information regarding the Company's projected revenue and anticipated growth, while failing to disclose: (i) risk from seasonality and macroeconomic fluctuations were underplayed; (ii) the Individual Defendants' model for growth relied too heavily, or otherwise overstated, hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies; (iii) as a result, there was a significant risk that TAVR's growth would decelerate; and (iv) the Company lacked internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times.
- 157. In further breach of their fiduciary duties, the Individual Defendants failed to correct and/or caused the Company to fail to correct the false and/or misleading statements and omissions of material fact referenced herein.
- 158. Moreover, in further breach of their fiduciary duties during the Relevant Period, the Individual Defendants willfully or recklessly caused the Company to repurchase millions of shares of its own common stock at artificially inflated prices before the fraud was exposed.
- 159. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls

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- 160. As a direct and proximate result of the Individual Defendants' failure to fulfill their fiduciary obligations, the Company has sustained significant damages.
- 161. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs incurred in defending itself in the Securities Class Action, exposing the Company to millions of dollars in potential class-wide damages in the Securities Class Action, and damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.
 - 162. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

COUNT IV

Against the Individual Defendants for Aiding and Abetting Breach of Fiduciary Duty

- 163. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 164. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual

Defendants have each encouraged, facilitated, and advanced their breach of their fiduciary duties. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the ultra vires and illegal conduct complained of herein.

165. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

COUNT V

Against the Individual Defendants For Unjust Enrichment

- 166. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 167. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Edwards.
- 168. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Edwards that were tied to the performance or artificially inflated valuation of Edwards, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.
- 169. Plaintiff, as a shareholder and a representative of Edwards, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits and other compensation procured by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.
 - 170. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

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COUNT VI

Against the Individual Defendants For Abuse of Control

- 171. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 172. The Individual Defendants misconduct alleged herein constituted an abuse of their control over the Company, for which they are legally liable.
- 173. As a direct and proximate cause of the Individual Defendants' abuse of control, the Company has sustained substantial damages.
 - 174. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

COUNT VI

Against the Individual Defendants For Waste of Corporate Assets

- 175. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 176. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.
- 177. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, *inter alia*: (i) paying and colleting excessive compensation and bonuses; and (ii) incurring potentially millions of dollars of legal liability and/or legal costs, including defending the Company and its officers against the Securities Class Action.
- 178. Additionally, the Individual Defendants caused the Company to repurchase shares of its own common stock at artificially inflated prices, thereby wasting the Company's assets.

- 179. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.
 - 180. Plaintiff, on behalf Edwards, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

- A. Awarding money damages against all Individual Defendants, jointly and severally, for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest, molded in a fashion to ensure the Individual Defendants do not participate therein or benefit thereby;
- B. Directing all Individual Defendants to account for all damages caused by them and all profits and special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all salaries, bonuses, fees, stock awards, options and common stock sale proceeds, and imposing a constructive trust thereon;
 - C. Awarding punitive damages;
- D. Awarding costs and disbursements of this action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
- E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: January 17, 2025 WOLF HALDENSTEIN ADLER FREEMAN & HERZ LLP

By: /s/ Alex J. Tramontano
ALEX J. TRAMONTANO
BETSY C. MANIFOLD
RACHELE R. BYRD
STEPHANIE AVILES

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28	VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT					

VERIFICATION

I, Barbara Sheridan, have reviewed the allegations made in this Verified Shareholder Derivative Complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true. I further declare that I am a current holder, and have been a holder, of Edwards Lifesciences Corporation common stock at all relevant times.

I declare under penalty of	perjury under the	laws of the United State	es that the foregoing is
	1/10/2025		
true and correct. Executed this	day of	2025.	
		Signe	•
		Barl	<u>rara Sheridan</u>
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